



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,240	11/13/2000	Mark E. Connell	ALT-5604D CON II of DIV I	6987

7590 04/11/2002

Paula J. F. Kelly, Esq
Baxter International, Inc.
One Baxter Parkway
Deerfield, IL 60015

EXAMINER

DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
1723	18

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/711,240	Applicant(s) CONNELL ET AL
	Examiner JOSEPH DRODGE	Art Unit 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Feb 13, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30-41 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30-41 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

Art Unit: 1723

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

Art Unit: 1723

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein patent 4,370,983 in view of Rubalcaba patent 4,898,578 and/or Kerns et al patent 4,756,706.

Lichtenstein discloses a computer controlled medical care system that encompasses extracorporeal blood circulation and treatment systems including means for conducting dialysis treatment of the blood in which numerous parameters are monitored, displayed and controlled through the use of central processing units coupled to interactive monitoring , input, and appropriate or standard interactive and display units (see especially column 28, lines 60-65 and column 32, lines 26-67. Also disclosed with the medical care system are modules for conducting intravenous and drug infusion for patients (see column 31, lines 12-33).

The independent claims each differ from Lichtenstein in requiring the interactive input/outputs to comprise touch screens. However, each of Kerns et al and Rubalcaba teach such interactive units employed with blood infusion pumping systems, operable to allow touch screen entry of keypads effective to change at least one step of a medical procedure (see especially column 8, lines 35-45 of Rubalcaba and column 1, lines 41-59 of Kerns et al. At the time the present invention was made, it would have been obvious to one of ordinary skill in this art to have modified the system of Lichtenstein by substituting or supplementing the alphanumeric units with such touch screen units, as taught by Rubalcaba and/ or Kerns et al, in order to ease

Art Unit: 1723

user confusion and error in entering data and prevent extra errors from occurring during crisis situations, as suggested by Rubalcaba and/or prevent confusion in entering data due to detachment and reattachment of components to the central processor, as suggested by Kerns et al.

Regarding dependent claim 35, all three references relied upon teach monitoring and control of a plurality of parameters which change both predictably and unpredictably with time.

Regarding claim 36, see Kerns et al in column 5, lines 56-59.

Regarding claims 38 and 39, Lichtenstein in column 12, lines 15-48 extensively concerns monitoring and control of blood flow in dialysis conduit systems containing blood pumps.

Response to Arguments

4. Applicant's arguments filed on February 13, 2002 have been fully considered but they are not persuasive.

Firstly, it is argued that the primary reference, Lichtenstein does not provide a teaching or suggestion to lead a skilled artisan to contemplate incorporating a touch screen or other use of complex computer control equipment with a hemodialysis or other extracorporeal system. It is submitted that Lichtenstein actually does teach incorporating a range of the most technologically advanced computerized control system equipment available at the time of filing of his patent application, including relatively advanced, interactive, user interface software and equipment, (see

Art Unit: 1723

especially column 4, lines 25-35, column 8, line 47-column 9, line 22, column 15, lines 32-41, column 28, lines 60-65 and column 32, line 26-column 33, line 32).

Secondly, it is argued that the teaching references, Kerns and Rubalcaba which do explicitly teach touch screen user interfaces, are drawn strictly to portable infusion pump, modular systems , not to extracorporeal blood treatment systems, hence to systems relatively more simple and requiring relatively less control parameters. It is submitted that Lichtenstein teaches a modular medical treatment system that may include varied forms of equipment to infuse fluids into patients , in combination with extracorporeal blood treatment and other medical treatments (see column 5, lines 34-59, especially lines 34-43).

Thirdly, it is argued that Lichtenstein does not suggest how to adapt a touch screen to the relatively more complex innovations that would be required with the hardware and software of the extracorporeal system Lichtenstein is concerned with. However, it is submitted that Lichtenstein already teaches interaction of a wide range of computerized equipment which is relatively advanced for the time period in which the Lichtenstein application was filed.

Next it is argued that neither Kerns or Rubalcaba provides any suggestion as to how to replace some or all of the electromechanical controls and displays with a functional touch screen. In reply, it is submitted that Kerns teaches touch screens being actually combined with other existing electromechanical controls and displays in column 5, lines 56-59, while Rubalcaba teaches use of a touch screen , in combination with what is referred to as "conventional microprocessor chip and programming memory and supporting circuitry" (see column 3, lines 28-51).

Art Unit: 1723

It is subsequently argued that neither teaching references teaches using a touch screen to monitor and control a multitude of complex parameters of a control management system or control internal set-up of multiple modules. It is submitted that the claims are silent as to requiring such specific touch screen functionality.

It is finally argued that the problem solved with use of the touch screens by the teaching references pertained to mitigating confusion and error resulting from a system in which multiple drug infusion modules are stacked, switched and rearranged. It is submitted that solving of such problem directly points to the benefits of employing touch screens with Lichtenstein's system since Lichtenstein also is directed to simultaneous operation of multiple modules of different types that perform different tasks and is similarly concerned with reliability and speed of data entry and transmissions (see column 1, lines 44-60 and column 2, line 41-column 3, line 7).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1723

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Drodge whose telephone number is (703) 308-0403. The examiner can normally be reached on Monday-Friday from approximately 8:30 AM - 4:45 PM.

The fax phone number for this Group is (703) 872-9310 or (703)-872-9311 for (after final rejections). When filing a FAX in Tech Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


Joseph W. Drodge
Primary Examiner
Art Unit 1723

JWD
April 7, 2002